DM was identified as a strong independent predictor of stroke (HR =3.09; 95% CI 1.52-6.29, p=0.002), TLR (HR=2.10; 95% CI 1.30-3.38, p=0.002) and TVR (HR =1.66; 95% CI 1.15-2.39, p=0.006).
Conclusions: Among this large series of consecutives pts undergoing LM PCI, DM was not associated with an increase in death or ST, but was independently predictive of stroke, TVR and TLR at 6-year follow-up.

TCT-417

Left Ventricular Assist Improves 90 Day Outcomes With Unprotected Left Main Coronary Intervention: Analysis From The Protect II Trial

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Background: Patients with severe left ventricular (LV) dysfunction undergoing intervention (PCI) upon the unprotected left main coronary (ULM) or the last remaining conduit (LRC) are susceptible to peri-procedural heart failure or hypotension which may limit the effectiveness of revascularization efforts.
Methods: The Protect II trial compared an LV assist device (Impella 2.5) to intra-aortic balloon counterpulsation (IABP) in patients undergoing high risk coronary intervention. We analyzed 90 day outcomes from the subset of study subjects treated with ULM or LRC intervention.
Results: A total of 448 patients were treated in the Protect II trial and of these 102 underwent ULM (34 Impella, 35 IABP) or another LRC (15 impella, 18 IABP) PCI per protocol definition. Of the ULM/LRC cohort (N= 102), 50% had class 3 or 4 heart failure, and the mean LVEF was 26%. Procedural differences between the two groups included a trend for more use of rotational atherectomy (RA), (22.4% vs 9.4%, p=0.071) with Impella; when RA was used, patients on Impella were treated with longer atherectomy runs (94.1 vs 36.5 sec, p=0.026). Duration of device support was much shorter (1.6 vs 10.8 hours, p=0.013) with Impella compared to IABP. Comparing 90 day composite major adverse cardiac and cerebrovascular events (MACCE) of death, large myocardial infarction (MI) with CK-MB > 8x normal, stroke, or repeat revascularization procedures, Impella use was associated with less MACCE compared to IABP use (16.7% vs 34.0%; p=0.047). The difference in MACCE was mainly driven by fewer strokes (0% vs 5.7%) and repeat procedures (0% vs 11.3%) with Impella.
Conclusions: In this subgroup analysis of a randomized trial, in patients with severe LV dysfunction undergoing PCI to the ULM or LRC, the use of Impella LV assist during intervention was associated with a lower risk of major adverse events at 90 days compared to the use of a IABP.

TCT-418

Confirmation of the Prognostic Capability of the SYNTAX Score-II Among 1,528 Patients who Underwent Left Main PCI

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Background: Recently, the SYNTAX score-2 (SxS-2) was developed in an attempt to individualize and help the decision-making process between percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG) in the management of complex coronary artery disease (CAD). We sought to evaluate and confirm the prognostic capacity of the SxS-2 among a group of 1,528 consecutive patients who already underwent left main (LM) PCI.
Methods: Data from all consecutive patients from a single center undergoing LM PCI were prospectively collected. Coronary angiograms and the resulting SYNTAX scores (SxS)/residual SxS were assessed by an independent angiographic core laboratory, and then the SxS-II derived for both PCI and CABG using patients' baseline clinical characteristics. Patients were divided and compared according to whether the SxS-II indicated PCI vs. CABG as the most favorable strategy of revascularization. Cumulative adverse ischemic outcomes, including death, were compared between the 2 groups.
Results: Among the study population of 1528 patients, 238 patients (15.6%) were deemed to be better candidates for CABG. Baseline and residual SxS were higher in CABG group compared with the PCI group (26.3±8.1 vs. 23.5±6.8, p<0.0001 and 6.0±7.4 vs. 4.1±5.5, p=0.0001, respectively). At a mean follow-up of 4.4 years, the CABG group had a non-significant trend toward higher death (6.7% vs. 4.7%, p=0.21), mainly driven by cardiac death (5.0% vs. 2.7%, p=0.07), and increased myocardial infarction (11.3% vs. 6.8%, p=0.02). Multivariate analysis showed CABG preference based on SxS-II to be an independent predictor of mortality (HR=4.13; [95% CI] [1.59, 10.7] p=0.004) after LM PCI.
Conclusions: Results from this large series of consecutive patients who underwent LM PCI retrospectively confirmed the prognostic capability of the SxS-II for mortality among patients with complex coronary artery disease.

TCT-419

Side branch patency after implantation of the novel DESolve bioresorbable vascular scaffold system in the treatment of de novo coronary lesions

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Background: Background: The DESolve® novolimus-eluting bioresorbable scaffold system (Elixir Medical Co., Sunnyvale, CA) is a novel bioresorbable vascular scaffold device that combines a PLLA-based scaffold (strut thickness 150 µm) coated with a potent antiproliferative sirolimus metabolite – Novolimus (5 µm per mm of scaffold length). Our aim was to investigate the occurrence of side branch (SB) compromise after implantation of the DESolve device in single de novo coronary lesions
Methods: Methods: 126 patients/lesions were prospectively enrolled in the multicenter (13 sites), non-randomized, single-arm DESolve Nx trial. Lesion criteria were < 14 mm in length located in a native coronary vessel measuring 2.75-3.5 mm in diameter. SB compromise, defined as vessel occlusion (TIMI flow 0/1) at post-procedure, was evaluated within the treated segment covered by the study device at an independent angiographic core laboratory. All SBs >1.0 mm in diameter (by visual estimation) were considered for analysis.
Results: Results: Overall, there were 71 SBs >1.0 mm found in 123 coronary segments treated by 126 scaffolds (3 lesions did not receive the study device; 3 lesions received 2 study devices). The majority of SBs (96%) had pre-procedure TIMI 3 flow. During the procedure, neither guide wire protection nor intervention was performed in any SB. At post-procedure, SB occlusion was detected in only 3 cases, representing a 4.2% SB compromise rate. Importantly, there were no adverse clinical events during hospitalization associated with SB occlusion.
Conclusions: Conclusions: In the prospective, non-randomized, single-arm, multicenter DESolve Nx trial, SB compromise – as determined by vessel occlusion after implantation of the novel DESolve bioresorbable vascular scaffold, was relatively low (4.2%) and was not associated with adverse clinical events during index hospitalization.

TCT-420

First- versus Second-generation Drug-Eluting Stents for the Treatment of Coronary Bifurcations

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Background: Randomized controlled trials have demonstrated that of second-generation drug-eluting stents (DES) for the treatment of obstructive coronary artery disease is associated with comparable, if not improved, clinical outcomes as compared to that of their first-generation counterparts. The aim of this study was to compare the long-term clinical outcomes associated with first- versus second-generation DES for the treatment of coronary bifurcation lesions.
Methods: This was a retrospective study of consecutive de novo bifurcation lesions, excluding those at the left main, treated with either second-generation DES (everolimus-eluting or zotarolimus-eluting stents) between October 2006-October 2011 (199 bifurcation lesions in 192 patients) or first-generation DES (sirolimus-eluting or paclitaxel-eluting stents) between April 2002-December 2005 (289 bifurcation lesions in 273 patients).
Results: Second-generation DES use in this setting was associated with less major adverse cardiac events (MACE) (23.1% vs. 14.4%, p= 0.02) as well as lower target vessel revascularization (TVR) rates (15.5% vs. 8.3%, p=0.01) at 2-year follow-up. Target lesion revascularization, both per patient (12.6% vs. 7.4%, p=0.02) and per bifurcation (11.8% vs. 7.0%, p=0.03), was also improved with second-generation DES over the same follow-up period. Propensity-score adjusted analysis suggested than first-generation DES was an independent predictor of both MACE (HR, 0.53; 95% CI, 0.33-0.85; p=0.01) and TVR (HR, 0.44; 95% CI, 0.24-0.83; p=0.01).
Conclusions: Our results suggest that the use of second-generation DES for the treatment of bifurcation lesions is associated with better clinical outcomes as compared to first-generation DES, largely due to a lower need for repeat revascularization.